Citation:

Mennella JA, Gerrish CJ. Effects of exposure to alcohol in mother's milk on infant sleep. *Pediatrics.* 1998 May; 101(5): E2.

PubMed ID: 9565435

Study Design:

Non-Randomized Controlled Trial

Class:

C - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine the hypothesis that exposure to alcohol in breast milk affects infants' sleep and activity levels in the short term.

Inclusion Criteria:

Fifteen non-smoking lactating women who had consumed at least one alcoholic beverage during lactation and whose infants had experienced drinking breast milk from a bottle.

Exclusion Criteria:

- Infants with fevers on testing days
- Infants who received vaccination injections the day before testing
- Infants who cried throughout the session.

Description of Study Protocol:

Recruitment

Advertisements in local newspapers and from the Women, Infant, and Children Centers in Philadelphia, PA.

Design

Cohort study.

Dietary Intake/Dietary Assessment Methodology

- Using a time-line follow-back questionnaire, each woman estimated the number, types and frequency of alcoholic beverages consumed during pregnancy and lactation. Mothers

reported drinking very little during pregnancy (range, zero to 30 alcoholic beverages per nine months; mean±SEM, 1.3±1.1), but increasing alcohol intake during lactation, on average, to 3.0±1.0 alcoholic beverages per month (range, one to 20 drinks per month); these numbers likely under-estimate alcohol usage.
- At the end of the study, mothers were asked to refrain from drinking one alcoholic beverage in the near future, so that their infant would not be additionally exposed to alcohol as a result of their participation in the study.

Statistical Analysis

- The following sleep-wake measures were derived from the activity raw data for each 3.5-hour test session:
  - Sleep percent (percentage of total minutes spent in sleep)
  - Quiet sleep (total minutes the infant spent in quiet sleep)
  - Active sleep (total minutes the infant spent in active sleep)
  - Longest sleep period (length of the longest continuous episode of sleep)
  - Latency to fall asleep (number of minutes to first sleep bout)
  - Number of sleeping bouts
  - Mean activity count (average number of zero crossings the piezoelectric beam) during wakefulness
- All summary statistics reported in this article are expressed as means±SEM, and all P-values represent two-tailed tests.

Data Collection Summary:

Timing of Measurements

Thirteen lactating women and their infants were tested on two days, separated by an interval of one week. On each testing day, the mother expressed 100ml of milk, while an actigraph was placed on the infant's left leg to monitor sleep and activity patterning. After the actigraph had been in place for 15 minutes, the infants ingested their mother's breast milk flavored with alcohol (32mg) on one testing day and breast milk alone on the other. The infants' behaviors were monitored for the next 3.5 hours.

Dependent Variables

- Infant's sleep level
- Infant's activity level.

Independent Variables

Exposure to alcohol in breast milk.

Description of Actual Data Sample:

- *Initial N:* 15
- *Attrition (final N):* 13
- *Age:*
  - Mothers (three primiparous, 10 multiparous) ranged in age from 22 to 34 years (mean, 27.4±1.1 years)

- Infants (nine girls, four boys) ranged in age from 1.5 to 5.6 months of age (mean, 2.7±0.3 months)
- *Location:* Philadelphia, PA.

Summary of Results:

Sleep and Activity Measures During the 3.5 Hours After the Infants' Ingestion of Breast Milk With Alcohol or With Breast Milk Alone(P≤0.5)

Variable	Type of Milk Ingested by Infant	
	Breast Milk	Alcohol-flavored Breast Milk
Total sleep (minutes)	78.2±10.6	56.8±11.0
Quiet sleep (minutes)	34.0±6.9	31.0±6.8
Active sleep (minutes)	44.2±5.9	25.8±5.1
Latency to first sleep bout (minutes)	50.4±7.7	34.1±6.1
Longest sleep bout (minutes)	56.7±10.8	34.5±6.6
Number of sleep bouts	2.8±0.5	2.4±0.4
Mean activity count during wakefulness	211.9±6.6	221.9±6.7

Author Conclusion:

Short-term exposure to small amounts of alcohol in breast milk produces distinctive changes in the infant's sleep-wake patterning.

Reviewer Comments:

None.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	N/A
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes

3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	N/A
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A

3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	Yes
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	N/A
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	Yes
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A

6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes

10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes